

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
WESTERN DIVISION

VINCENT GILLESPIE
AND DOES 1-100,

Plaintiffs,

v.

ELI LILLY AND COMPANY
AND DOES 1-100,

Defendants.

) Civil Action No. 03-CV-30196 (KPN)
)
) JURY TRIAL DEMANDED
)
) DEFENDANT ELI LILLY AND
) COMPANY'S ANSWER TO
) PLAINTIFFS' COMPLAINT
)
)
)

ANSWER

Defendant Eli Lilly and Company ("Lilly"), for its Answer to plaintiffs' Complaint, alleges and states as follows:

1. Lilly is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in the paragraph 1 of plaintiffs' Complaint and therefore denies the same.

1.[sic] Lilly admits that it is an Indiana corporation with its principal place of business in Indianapolis, Indiana and that it does business in the Commonwealth of Massachusetts.

2. Lilly is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 2 of plaintiffs' Complaint and therefore denies the same.

3. Paragraph 3 of plaintiffs' Complaint contains no allegations to which a response is required. To the extent a response is required, Lilly denies the allegations contained in paragraph 3 of plaintiffs' Complaint.

4. Lilly admits the allegations contained in paragraph 4 of plaintiffs' Complaint.

5. Paragraph 5 of plaintiffs' Complaint contains no allegations to which a response is required. To the extent a response is required, Lilly is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 5 of plaintiffs' Complaint and therefore denies the same.

6. Lilly is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 6 of plaintiffs' Complaint and therefore denies the same.

7. Lilly is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 7 of plaintiffs' Complaint and therefore denies the same.

8. Lilly admits that, during its controlled clinical trials of fluoxetine hydrochloride, certain adverse effects were reported with greater frequency in patients taking fluoxetine than in patients taking placebo. Lilly further admits that those events are listed (with frequency of occurrence) in its FDA-approved product labeling. Further answering, Lilly states that the phrase "typical symptoms of the adverse side effects of Prozac" is too vague to be answerable. To the extent the pronoun "he" refers to Gregory Gillespie, Lilly is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning medical events allegedly experienced by Gregory Gillespie, and therefore denies the same. Lilly denies all remaining allegations in paragraph 8, including those allegations set forth in subparagraphs 8.1 – 8.3.

9. Lilly denies the allegations contained in paragraph 9 of plaintiffs' Complaint.

COUNT I

10. Lilly is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 10 concerning plaintiff Vincent Gillespie's legal standing with regard to the Estate of Gregory Gillespie and therefore denies all allegations regarding the same. Further answering, Lilly repeats and realleges its answers to paragraphs 1 through 9 of plaintiffs' Complaint as though fully set forth herein. Lilly denies all remaining allegations contained in paragraph 10 of plaintiffs' Complaint.

11. The allegation in paragraph 11 of plaintiffs' Complaint that Lilly "owed a duty of care, protection, and safety to Gregory Gillespie" merely recites plaintiffs' own legal conclusions to which no response is required. To the extent a response is required, Lilly admits the existence duties properly imposed upon it by applicable law and denies all remaining allegations contained in paragraph 11 of plaintiffs' Complaint.

12. Lilly denies the allegations contained in paragraph 12 of plaintiffs' Complaint.

13. Plaintiffs' allegation in paragraph 13 of the Complaint that "[t]his count is for wrongful death pursuant to M.G.L. c. 229 § 2" merely recites plaintiffs' own legal conclusions to which no response is required. To the extent a response is required, Lilly denies that portion of paragraph 13 of plaintiffs' Complaint quoted above. Further answering, Lilly is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 13 of plaintiffs' Complaint concerning plaintiff Vincent Gillespie's legal standing with regard to the Estate of Gregory Gillespie and therefore denies all allegations regarding the same. Lilly admits that plaintiffs seek the relief requested in paragraph 13 of

plaintiffs' Complaint, but denies that plaintiffs are entitled to any such relief from Lilly. Lilly denies all remaining allegations contained in paragraph 13 of plaintiffs' Complaint.

Further answering, Lilly is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in the WHEREFORE paragraph following paragraph 13 of plaintiffs' Complaint concerning plaintiff Vincent Gillespie's legal standing with regard to the Estate of Gregory Gillespie and therefore denies all allegations regarding the same. Lilly admits that plaintiffs seek the relief requested in the WHEREFORE paragraph following paragraph 13 of plaintiffs' Complaint, but denies that plaintiffs are entitled to judgment against, or any such relief from, Lilly.

COUNT II

14. Lilly is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 14 of plaintiffs' Complaint concerning plaintiff Vincent Gillespie's legal standing with regard to the Estate of Gregory Gillespie and therefore denies all allegations regarding the same. Further answering, Lilly repeats and realleges its answers to paragraphs 1 through 13 of plaintiffs' Complaint as though fully set forth herein. Lilly denies all remaining allegations contained in paragraph 14 of plaintiffs' Complaint.

15. The allegation in paragraph 15 of plaintiffs' Complaint that Lilly "owed a duty of care, protection, and safety to Gregory Gillespie" merely recites plaintiffs' own legal conclusions to which no response is required. To the extent a response is required, Lilly admits the existence duties properly imposed upon it by applicable law and denies all remaining allegations contained in paragraph 15 of plaintiffs' Complaint.

16. Plaintiffs' allegation in paragraph 16 of the Complaint that "[t]his count is for Conscious Pain and Suffering pursuant to M.G.L. c. 229 § 6" merely recites plaintiffs' own legal conclusions to which no response is required. To the extent a response is required, Lilly

denies that portion of paragraph 16 of plaintiffs' Complaint quoted above. Further answering, Lilly is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 16 of plaintiffs' Complaint concerning plaintiff Vincent Gillespie's legal standing with regard to the Estate of Gregory Gillespie and therefore denies all allegations regarding the same. Lilly admits that plaintiffs seek the relief requested in paragraph 16 of plaintiffs' Complaint, but denies that plaintiffs are entitled to any such relief from Lilly. Lilly denies all remaining allegations contained in paragraph 16 of plaintiffs' Complaint.

17. Lilly denies the allegations contained in paragraph 17 of plaintiffs' Complaint.

18. Lilly denies the allegations contained in paragraph 18 of plaintiffs' Complaint.

Further answering, Lilly is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in the WHEREFORE paragraph following paragraph 18 of plaintiffs' Complaint concerning plaintiff Vincent Gillespie's legal standing with regard to the Estate of Gregory Gillespie and therefore denies all allegations regarding the same. Lilly admits that plaintiffs seek the relief requested in the WHEREFORE paragraph following paragraph 18 of plaintiffs' Complaint, but denies that plaintiffs are entitled to judgment against, or any such relief from, Lilly.

COUNT III

19. Lilly repeats and realleges its answers to paragraphs 1 through 18 of plaintiffs' Complaint as though fully set forth herein.

20. Lilly denies the allegations contained in paragraph 20 of plaintiffs' Complaint.

21. Lilly denies the allegations in contained paragraph 21 of plaintiffs' Complaint.

22. Lilly denies the allegations in contained paragraph 22 of plaintiffs' Complaint.

23. Lilly denies the allegations contained in paragraph 23 of plaintiffs' Complaint.

Further answering, Lilly is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in the WHEREFORE paragraph following paragraph 23 of plaintiffs' Complaint concerning plaintiff Vincent Gillespie's legal standing with regard to the Estate of Gregory Gillespie and therefore denies all allegations regarding the same. Lilly admits that plaintiffs seek the relief requested in the WHEREFORE paragraph following paragraph 23 of plaintiffs' Complaint, but denies that plaintiffs are entitled to judgment against, or any such relief from, Lilly.

COUNT IV

24. Lilly repeats and realleges its answers to paragraphs 1 though 23 of plaintiffs' Complaint as though fully set forth herein.

25. Lilly denies the allegations contained in paragraph 25 of plaintiffs' Complaint.

26. Lilly denies the allegations contained in paragraph 26 of plaintiffs' Complaint.

Further answering, Lilly is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in the WHEREFORE paragraph following paragraph 26 of plaintiffs' Complaint concerning plaintiff Vincent Gillespie's legal standing with regard to the Estate of Gregory Gillespie and therefore denies all allegations regarding the

same. Lilly admits that plaintiffs seek the relief requested in the WHEREFORE paragraph following paragraph 26 of plaintiffs' Complaint, but denies that plaintiffs are entitled to judgment against, or any such relief from, Lilly.

COUNT V

27. Lilly repeats and realleges its answers to paragraphs 1 through 26 of plaintiffs' Complaint as though fully set forth herein.

28. Lilly denies the allegations contained in paragraph 28 of plaintiffs' Complaint.

Lilly is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in the WHEREFORE paragraph following paragraph 28 of plaintiffs' Complaint concerning plaintiff Vincent Gillespie's legal standing with regard to the Estate of Gregory Gillespie and therefore denies all allegations regarding the same. Lilly admits that plaintiffs seek the relief requested in the WHEREFORE paragraph following paragraph 28 of plaintiffs' Complaint, but denies that plaintiffs are entitled to judgment against, or any such relief from, Lilly.

Further answering, Lilly states that the unnumbered sentence following paragraph 28 of plaintiffs' Complaint contains no allegations to which a response is required. To the extent a response is required, Lilly also demands a trial by jury as to all issues.

Lilly denies each and every allegation not specifically admitted herein.

PREAMBLE TO AFFIRMATIVE AND OTHER DEFENSES

Lilly reserves the right to rely upon any of the following or additional defenses to claims asserted by plaintiffs to the extent that such defenses are supported by information developed through discovery or evidence at trial.

FIRST AFFIRMATIVE DEFENSE

Plaintiffs' Complaint, in whole or in part, fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

Plaintiffs' Complaint fails to state a claim upon which relief in the form of punitive damages can be granted.

THIRD AFFIRMATIVE DEFENSE

The claims asserted by plaintiffs may be barred by the applicable statute or statutes of limitations.

FOURTH AFFIRMATIVE DEFENSE

If plaintiffs sustained injuries or incurred expenses, the same were caused, in whole or in part, by the acts and omissions of the plaintiffs, plaintiffs' decedent, or others for whose conduct Lilly is not responsible and whose conduct Lilly had no reason to anticipate.

FIFTH AFFIRMATIVE DEFENSE

If plaintiffs sustained the injuries or incurred the expenses alleged, there was an intervening cause and/or causes leading to such alleged injuries, and any action or omission on the part of Lilly was not the proximate cause of plaintiffs' alleged injuries.

SIXTH AFFIRMATIVE DEFENSE

If plaintiffs suffered or sustained any loss, damage, injury, harm, expense, diminution, or deprivation alleged, the same may have been caused in whole or in part or contributed to by plaintiffs' or decedent's own negligence or intentional conduct or by the expressed or implied assumption of the risk by one or all of them.

SEVENTH AFFIRMATIVE DEFENSE

The imposition of punitive damages in this case would violate the Fourth, Fifth, Eighth, and Fourteenth Amendments to the United States Constitution and applicable provisions of the Constitution of the State of Massachusetts. Additionally, the Contracts Clause of Article I, Section 10 of the United States Constitution, bars punitive damages.

EIGHTH AFFIRMATIVE DEFENSE

Prozac® has been approved as a prescription medical product by the United States Food and Drug Administration and has been tested, manufactured, and labeled in accordance with FDA standards, pursuant to 21 U.S.C. § 301 *et seq.* Consequently, plaintiffs' claims are barred in whole or in part by the doctrine of preemption under the Supremacy Clause of the United States Constitution.

NINTH AFFIRMATIVE DEFENSE

The methods, standards, and techniques utilized by Lilly in developing and manufacturing the product in question and in issuing warnings and instructions with respect to its use conformed with the generally recognized, reasonably available and reliable state of knowledge at the time the product was manufactured.

TENTH AFFIRMATIVE DEFENSE

To the extent plaintiffs asserts that Lilly failed to provide an adequate warning to plaintiffs' decedent with respect to the use of the prescription drug Prozac®, Lilly states that any obligation to warn plaintiffs' decedent was discharged through the provision of an adequate warning including, but not limited to, its indications, contraindications, warnings, precautions, and adverse reactions to the plaintiffs' decedent's treating and prescribing physicians and plaintiffs' claims are therefore barred by the learned intermediary doctrine.

ELEVENTH AFFIRMATIVE DEFENSE

Any and all damages alleged by plaintiffs may have been caused by misuse, abuse, or unintended or unforeseeable use of Prozac®, failure to use Prozac® properly, alteration or negligent use of Prozac® and consequently no act or omission on the part of Lilly proximately caused any of plaintiffs' claimed injuries or damages.

TWELFTH AFFIRMATIVE DEFENSE

The injuries or the expenses alleged by plaintiffs may have been caused, in whole or in part, by an idiosyncratic reaction, operation of nature or act of God, or by pre-existing and/or unrelated medical, genetic, and/or environmental conditions, diseases or illnesses of plaintiffs' decedent.

THIRTEENTH AFFIRMATIVE DEFENSE

Prozac® is a prescription drug that falls with Restatement (Third) of Torts: Products Liability § 6. Prozac® is therefore reasonably safe in design if a reasonable health care provider would prescribe Prozac® to any class of patients. At all times material to the Complaint, Prozac® was accompanied by reasonable instructions and warnings to the prescribing physician and other health-care providers.

FOURTEENTH AFFIRMATIVE DEFENSE

The benefits of Prozac® outweigh the risks, if any, which may be attendant to its use.

FIFTEENTH AFFIRMATIVE DEFENSE

Lilly reserves its right to make a written election of credit for settlements under the applicable law. Lilly further demands that its fault or responsibility be compared to other parties and non-parties to this suit as provided by any governing statutory or common-law scheme of comparative fault, comparative responsibility, and contribution.

SIXTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims against Lilly may be barred by the equitable doctrine of laches.

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiff may have failed to join identifiable and indispensable parties necessary for proper adjudication and/or may not be the real party in interest who has a right to prosecute the claims asserted.

EIGHTEENTH AFFIRMATIVE DEFENSE

Plaintiff Vincent Gillespie may lack capacity and/or standing to sue.

NINETEENTH AFFIRMATIVE DEFENSE

Prozac® is a prescription medical product that falls within the "comment *k*" and "comment *j*" exceptions to strict liability, as defined in *Restatement (Second) of Torts*, § 402A. Prozac® is therefore neither defective nor unreasonably dangerous when properly prepared and accompanied by proper warnings and instructions for use. At all times material to plaintiffs' Complaint, Prozac® was properly prepared and accompanied by proper warnings and instructions for use in accordance with generally recognized and prevailing standards in existence at the time.

TWENTIETH AFFIRMATIVE DEFENSE

Plaintiffs' claims may be barred by the doctrines of waiver, estoppel and judicial estoppel.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred because plaintiffs' service of process upon Lilly was insufficient, in that, *inter alia*, plaintiffs failed to serve a summons with the Complaint as required by Mass. R. Civ. P. 4(a) and Fed. R. Civ. P. 4(c)(1).

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs failed to state a claim upon which relief can be granted in that plaintiffs asserted claims for relief which, if granted, would constitute an invalid burden by this Court upon interstate commerce and a burden without resort to less burdensome alternatives, in violation of the Commerce Clause, Article I, Section 8 of the United States Constitution.

TWENTY-THIRD AFFIRMATIVE DEFENSE

If any loss, damage, injury, harm, expense, diminution or deprivation alleged by plaintiffs was caused by any product manufactured by Lilly, which Lilly denies, the actions of other persons and the independent knowledge and awareness of such other persons of the risks inherent in the use of such product constitute an intervening cause between plaintiffs' decedent alleged injuries and any alleged acts, conduct or omissions of Lilly.

Lilly reserves the right to amend this Answer and to add affirmative defenses after it has had an opportunity to discover all facts relevant to this action.

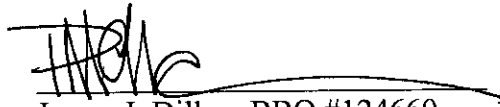
WHEREFORE, Lilly requests that this Court enter judgment in favor of Lilly and against plaintiff, dismissing plaintiffs' claims with prejudice and further awarding Lilly its costs and such other and further relief to which Lilly may be entitled.

JURY DEMAND

Lilly demands a trial by jury as to all issues.

Respectfully submitted,

By its attorneys:

A handwritten signature in black ink, appearing to read 'J. Dillon', is written over a horizontal line.

James J. Dillon, BBO #124660

Paula M. McManus, BBO #648029

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**ATTORNEYS FOR DEFENDANT
ELI LILLY AND COMPANY**

CERTIFICATE OF SERVICE

I hereby certify that on this 11th day of August, 2003, a true and correct copy of Defendant Eli Lilly and Company's Answer to Plaintiffs' Complaint was mailed via first class U.S. Mail, postage prepaid thereon, to the following *pro se* plaintiff:

Vincent Gillespie
P.O. Box 741
Northampton, MA 01027


**ATTORNEY FOR DEFENDANT
ELI LILLY AND COMPANY**